FDA 510(k) Premarket Notification

K070134 MODIFICATION TO STIMUPLEX HNS-12, MODEL 4892098

CLEARED

Mar 22, 2007
65 days to decision

K070134 · Product code: **BXN** · Anesthesiology
Source: https://www.510kdatabase.net/k070134/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve, Battery-powered (BXN)
Date received	Jan 16, 2007
Decision date	Mar 22, 2007
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stockert GmbH**
Location	Freiburg, DE
Contact	DOMINIKA SCHULER
510(k) history	5 submissions · 5 cleared · 2001-2007